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TITLE: "A Randomized Clinical Trial of the collaborative Assessment and Management of Suicidality vs. Enhanced Care as Usual for Suicidal Soldiers"

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
This Randomized Clinical Trial (RCT) will compare the effectiveness of CAMS versus Enhanced Care As Usual (E-CAU) in a sample of n = 150 active-duty Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions will be recruited from the Army Research Site (ARS), Fort Stewart, GA, and will be trained and monitored for fidelity and adherence to their respective treatment condition by the study staff. Participants are recruited from a number of sources at the ARS including the outpatient behavioral health clinic and the inpatient unit. Approvals from all IRB committees involved in the study have been obtained. Participant recruitment began in MAY 2012 for the training phase of the study; intent-to-treat phase of the study began in FEB 2013.

15. SUBJECT TERMS
Suicide Risk Assessment, Suicide Risk Management, an Suicide Treatment

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INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This study is investigating the effectiveness of a novel clinical intervention developed by the PI called the Collaborative Assessment and Management of Suicidality (CAMS). CAMS is not a new psychotherapy. Rather, CAMS is a therapeutic clinical framework with a distinct clinical philosophy and a set of structured procedures that enhance the therapeutic alliance and increase treatment motivation in the patient. This Randomized Clinical Trial (RCT) will compare the effectiveness of CAMS versus Enhanced Care As Usual (E-CAU) in a sample of n = 150 active-duty Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions will be recruited from the Army Research Site (ARS), Fort Stewart, GA, and will be trained and monitored for fidelity and adherence to their respective treatment condition by the study staff. Participants are being recruited from a number of sources at the ARS to include the behavioral health clinic and the inpatient unit. The goal of this study is to determine if CAMS is more effective than E-CAU in reducing suicidal ideation and behaviors (and various secondary variables such as overall symptom distress, Emergency Department utilization), as well as returning Soldiers to a fully mission capable status in comparison to Soldiers who receive E-CAU.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

As of Year 1, the research team had primarily been engaged in gaining IRB approvals from each of the IRB committees involved: Dwight D. Eisenhower Army Medical Center (DDEAMC), the Department of Veterans Affairs Veterans Integrated Service Network 19 Mental Illness Reseach, Education, and Clinical Center (VA VISN 19 MIRECC), the University of Washington (UW), and The Catholic University of America (CUA). The research team was successful in obtaining approval from all of the IRB committees, but this process took longer than anticipated and pushed back the hiring and training of staff and therapists, as well as the recruitment of participants, approximately one year later than initially proposed in the Statement of Work (SOW).

The initially proposed timeline of activities is included below:

Timeline of Study Activities Over Four Years																
	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X							
Training of therapists		X														
Recruitment of training cases		X	X													
Supervision of therapists adherence		X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases			X	X	X	X	X	X	X	X	X	X				
Baseline assessments			X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted			X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis					X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results									X	X	X	X	X	X	X	X

Based on the unanticipated delays in gaining IRB approval, the following table is a current updated timeline of the project. Due to the delays in gaining IRB approvals, initial difficulties with in-processing the study staff onto the ARS, and difficulties with retention among the clinical research therapists due to the high turnover rate of staff at the ARS, the table below is an updated timeline of study activities that reflects the realities of these difficulties in conducting the study:

Timeline of Study Activities Over Four Years																				
	Year 1				Year 2				Year 3				Year 4				NCE Year (if needed)			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X				X							
Training of therapists					X	X														
Recruitment of training cases					X	X	X													
Supervision of therapists adherence					X	X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases					X	X	X	X	X	X	X	X	X	X	X	X				
Baseline assessments					X	X	X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted					X	X	X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis									X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results													X	X	X	X	X	X	X	X

In the first quarter of the project year (Year 2), the CUA team conducted several site visits to the ARS to provide initial orientation and training for the research clinicians who had volunteered to participate in the study. The CUA team provided a half-day orientation training to the research theapists who would be providing care in the E-CAU condition of the study. An initial Data Safety Monitoring Board (DSMB) meeting was held to provide guidance to the research team on any participant-related study concerns and the handling of adverse events going forward (our second DSMB meeting is scheduled in the first quarter in current Year 3).

Dr. Katherine Comtois, the Co-PI from the University of Washington, and the on-site Participant Coordinator, Ms. Gretchen Ruhe, provide regular consultation and have regular interaction with the E-CAU therapists to ensure that the study team is providing needed resources for them to participate in the study. The CUA team continues to view the E-CAU therapy sessions to ensure fidelity to treatment condition and make sure that research clinicians are in fact providing E-CAU to study participants as outlined in the project's statement of work (SOW).

The CUA team also provided two separate 2-day trainings for the research therapists in the CAMS treatment condition to orient these clinicians to the study and to ensure that they were able to provide the experimental treatment as defined in the SOW. The CUA team and the on-site Participant Coordinator provide regular consultation and have regular interaction with the CAMS therapists to ensure that the study team is providing needed resources for them to participate in the study. The CUA

team continues to view the CAMS therapy sessions to ensure the fidelity and the adherence of the CAMS intervention that the clinicians are providing to the study participants.

The study team continues to hold bi-weekly conference calls to coordinate and evaluate study progress as an entire team. These calls have focused on further refining the procedures for administering the baseline and follow-up assessments with research participants, refining and making the implementation of the treatment protocols and the CAMS training manual more user-friendly, as well as problem-solving general administrative and site-specific difficulties that have arisen at different points in the project year.

Recruitment and training of the research therapists was done in the first quarter of the project year. The study team has continued to recruit additional research therapists to account for turnover due to deployments and staff members leaving the ARS. The CUA team is planning to conduct another site visit to the ARS in the first quarter of year 3 to provide additional orientation and training to newly recruited research clinicians for both treatment conditions.

The PI conducted a separate site visit during the project year to aid in coordination of the research clinician recruitment, and to coordinate with Army leadership at the ARS to problem-solve various friction points that had arisen concerning the various clinics from which the study was recruiting. Specifically, there was some confusion among staff on the ARS's inpatient unit regarding recruitment for

this study and for another epidmiological study that is also being conducted at the ARS. The PI was able to aid the Participant Coordinator in communicating the differencs between the studies to Army leadership at the site and ensure a smooth recruitment process. During this same site visit, the PI also visited a satellite location of the ARS (Hunter Army Airfield [HAAF]) to recruit additional research clinicians and expand services to additional personnel in need. The providers in the HAAF clinic expressed interest in the study and are the focus of an upcoming training to open this potential recruitment source for the study.

During this project year (Year 2), the 1.0 FTE Participant Coordinator finished in-processing and became fully credentialed at the site. The 1.0 FTE Backfill Clinician and the 0.8 FTE Backfill Clinician were also hired and became fully credentialed and providing clinical services at the site during the 2nd quarter of the project year. Recruitment and hiring of the 1.0 FTE Research Assistant was also conducted during the 4th quarter of the project year. This final study staff position was hired and is projected to begin work in the first quarter of the project's year 3 (MAR 2013).

All of the study staff that have been hired to date have been famliarized with the site's policies and procedures to facilitiate particpant recruitment. The Participant Coordinator conducted intensive training with the UW team and continues to conduct daily conference calls with the project's recruitment and assessment team at UW. Additionally, the Participant Coordinator has regular contact with the study PI to include a regular standing, weekly conference call.

The task list from the project's SOW is listed below in an effort to provide a task by task status update on progress made in the study, as well as to provide updated revisions to the anticipated timeline of various tasks. Status updates and revised timelines are included in italics following the original task from the SOW.

Task 1: Prepare study manuals for CAMS and Enhanced Care as Usual (E-CAU) Groups. (Year 1, Months 1-6).

Completed. Following the initial trial implementation, minor revisions to these manuals have been made in accordance with feedback from the research clinicians and from the CUA fidelity and adherence team who have been evaluating all sessions in accordance with the SOW. These minor revisions have included obtaining IRB approval to have family members engaged in treatment if the provider determines that this is clinical indicated and to update the CAMS Rating Scale to better capture some aspects of the experimental treatment in the manner that the research clinicians are being evaluated for adherence to the treatment.

1a: Review existing written materials regarding CAMS. (Year 1 Months 1-3)

Completed.

1b: Review existing Usual Care Model at **"*Army Research Site" (hereafter referred to as ARS)*** (Year 1 Months 1-3)

Completed.

1c: Regular (e.g., 2 per month) group meetings regarding key manual components (Year 1 Months 1-5)

Completed.

1d: Condense key components and write text of first drafts (Year 1 Months 2-3)

Completed.

1e: Review of drafts by senior research team members, outside experts, and study clinicians for 1) readability, 2) comprehensiveness, and 3) feasibility (Year 1 Months 3-4)

Completed.

1f: Manual revision based upon feedback to produce final version (Year 1 Months 5-6)

Completed.

Task 2: Hire and train study staff; modifications with training cases. (Year 1 Months 1-6)

On-going. The 1.0 FTE Participant Coordinator, the 1.0 FTE Backfill Clinician, and the 0.8 FTE Backfill Clinician were all hired, in-processed at the ARS, became fully credentialed at the ARS, and received all necessary training during Year 2. The final study hire, the 1.0 FTE Research Assistant was hired in the final quarter of Year 2 and it is anticipated that she will be fully in-processed and credentialed at the ARS, as well as fully trained in her duties and responsibilities, no later than the first quarter of Year 3.

2a: Select or hire Participant Coordinator (PC), and study therapist FTE to supplement existing *ARS* staffing for study. University of Washington (UW) Co-PI and Research Coordinator (RC) hire research assistant (RA) for follow-up assessments. (Year 1 Month 1-3)

Participant Coordinator, and study therapists (1.0 and 0.8 FTE Backfill Clinicians) have been hired and trained. The 1.0 FTE Research Assistant has been hired and will be trained in the first quarter of Year 3.

2b: UW CO-PI and RC train PC and RA in human subjects and other research protections, study policies and procedures, and administering study assessments. (Year 1 Month 2-3)

Completed for PC. To be completed for RA in next quarter.

2c: UW Co-PI and RC train ***ARS*** PC in recruiting procedures and develop adaptations to fit *ARS* context and environment (Year 1 Months 1-6)

Completed.

2d: Study therapists are matched to treatment condition and PI and CUA staff train CAMS therapists in CAMS as well as human subjects and other research protection and study policies and procedures (Year 1 Month 3)

Completed in first quarter of Year 2. As delineated in the SOW, this was anticipated to be an on-going process to account for research clinician turnover. Following from this consideration, the study team has continued to recruit additional study therapists, matching them to treatment condition, and will train the additional CAMS therapists in the first quarter of Year 3.

2e: PC begins recruitment and assessment procedures for training cases in CAMS. UW staff work with PC on effectiveness of recruitment procedures in ***ARS*** context and develop adaptations as needed prior to RCT intent to treat cases. (Year 1 Month 3-6)

Completed. Participant recruitment began in the 1st quarter of Year 2. Adaptations were made to recruitment procedures following lessons learned from the training cases and the study team began recruiting actual intent to treat (ITT) cases in the fourth quarter of Year 2. ITT recruitment is currently on-going.

2f. CAMS and E-CAU clinicians receive training with draft version of manuals and provide feedback to senior research team members (Year 1 Month 3)

Completed.

2f: CAMS study therapists see training cases with supervision and adherence ratings from PI and CUA staff. Modifications to CAMS appropriate to ***ARS*** context are identified, implemented, and codified in supplementary manual for clinical trial (Year 1 Month 3-6)

Completed.

2g: Enhanced Care as Usual (E-CAU) study therapists see training cases to pilot the intervention. Modifications to E-CAU appropriate to ***ARS*** context are identified, implemented, and codified into E-CAU treatment manual. (Year 1 Month 3-6)

Completed.

2h: UW RA begins follow-up assessments with training cases and UW Co-PI, and RC (with consultation from PI, co-PIs, and statistical consultant) develop any modifications to the tracking and assessment procedures, if needed. (Year 1 Month 4-6)

Completed. Follow-up assessments are on-going as the follow-up period is 12 months following recruitment.

2i: UW Co-PI and Denver VA MIRECC Co-PIs (with consultation from PI, ***ARS*** Co-PIs, RC, PC, and statistical consultant) evaluate feasibility and value of assessment battery as implemented with training cases and make needed changes in format, length, etc. to assure a viable assessment battery is established (Year 1 Month 3-6)

Completed.

2k: Final versions of CAMS and E-CAU manuals reviewed with study clinicians (Year 1 Months 5 -6)

Completed. The study team is modifying the adherence scale (CAMS Rating Scale) for the CAMS condition and anticipates submitting a revision for IRB approval sometime in the second quarter of year 3.

Task 3: Implementation of clinical trial and follow-up of Soldiers of Concern (SOC) (Year 1 Month 7 through Year 3 Month 12)

On-going. Implementation of the clinical trial (ITT phase), began in the 3rd quarter of Year 2 and will continue until n = 150 participants have been recruited.

3a: PC recruits study participants and assures fast and efficient randomization and matching to study therapists for first session (Year 1 Month 7 through Year 3 Month 12)

On-going.

3b: CAMS and E-CAU therapists follow their respective manuals to treat randomized participants (Year 1 Month 7 through Year 3 Month 12)

On-going.

3c: UW team conducts follow-up assessments ***using the University of Washington Risk Assessment Protocol (UWRAP) to address suicide risk during follow-up*** *(*Year 1 Month 8 through Year 4 Month 12).

On-going.

3d: ***PI and CUA staff will*** conduct ongoing adherence evaluation of CAMS study therapists and provide feedback and supervision to assure CAMS therapists remain adherent—***consultation by MIRECC Co-PI's will be used on complex cases (e.g., TBI and PTSD)*** (Year 1 Month 7 through Year 4 Month 3).

On-going.

3e: With consultation from statistical consultant, ***the UW site*** establishes final database systems and data entry and cleansing procedures appropriate to data collected. ***All pre-treatment and adherence data will be transported by HIPAA secure means to UW site to be entered and maintained.*** Data entry occurs in an ongoing basis (Year 1 Month 7 through Year 4 Month 12).

On-going.

3f: With assistance of the PC and *ARS* co-PIs establish and implement procedures for reviewing Army records for study participants and extracting this data ***which will be transported by HIPAA secure means to UW site. This data will be matched to study collected data in consultation with UW PI and statistical consultant.*** With consultation of PI, Co-PIs, and statistical consultant, the data and procedures used to extract medical records will be reviewed and modifications made, if needed, to assure viable data extraction access and procedures are established (Year 2 Month 1-12).

This process is on-going and the initial policies and procedures that have been established in coordination with the Army personnel at the ARS will be updated as required during the implementation of the study.

Task 4: Hiring and training of additional or replacement staff, if needed (Years 2-4)

4a: PI provides CAMS training to any additional or replacement CAMS study therapists, if needed, to assure sufficient flow through clinical trial (Year 2 Month 1 and Year 3 Month 1). Supervision of CAMS therapists will continue. (Year 2 Month 1 through Year 4 Month 3).

On-going. Next planned training for CAMS condition therapists is scheduled for the 1st quarter of Year 3 (MAY 2013). Supervision and consultation with CAMS therapists is on-going, with the CUA team providing 1-hour long, weekly conference calls to the CAMS therapists.

Task 5: Data analysis and dissemination of results (Years 3 and 4)

This task is currently scheduled to begin as originally planned in the upcoming project year, Year 3.

5a: Aim I: In consultation with PI, Co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze data from ongoing follow-up of suicidal individuals enrolled in trial to establish a recommended assessment battery from the briefest possible screening tools through an expanded assessment. Data will be compared with that collected in Army record to evaluate the reliability and validity of Army measures as compared to full research battery. (Years 3 and 4)

5b: Presentations, reports, publications prepared reflecting analyses of Aim 1 (Years 3 and 4)

5c: Aim II: In consultation with PI, co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze clinical trial data to evaluate effectiveness of CAMS from hypotheses (Year 4)

5d: Presentations, reports, and publications will be prepared reflecting the clinical trial results of Aim II hypotheses. (Year 4)

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

- The research team has finalized a new version of the Suicide Status Form (SSF) to be used in this study, the SSF-IV. The SSF is the primary clinical tool used in CAMS for assessing, managing, treating, and tracking suicidal risk in patients.

- The research team has developed a revised manual for conducting CAMS with patients who are suicidal.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include: manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award

There are not yet any reportable outcomes associated with this research. The intent-to-treat phase of this project recently began in the 4th quarter of the previous project year (FEB 2013). It is anticipated that initial data analyses will be conducted with the data collected during the initial training phase of the study (MAY 2012 – JAN 2013) during the upcoming project year.

Data from the training/implementation phase of the project will be based upon the following recruitment numbers:

Particpants approached: 55

Participants consented: 37

Participants who were eligible and randomized to treatment: 22

Current recruitment numbers for the intent-to-treat phase of the study are as follows:

Particpants approached: 13

Participants consented: 8

Participants who are eligible and randomized to treatment: 3

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

As data analysis has not yet been conducted, there are not yet any reportable outcomes associated with this research, and therefore no conclusions to draw at this time. The team expects to have reportable outcomes and associated conclusions during the next project year based upon analyses of the initial 22 training cases that were randomized and treated in the context of the training/implementation phase of the study. As the intent-to-treat phase of the project has only recently begun, initial analyses of these outcome data are not projected to begin until Year 4 of the study. Given the lengthy IRB review process (including various IRB modifications) and the size and scope of this study, it has taken longer than expected to enter into the intent-to-treat phase of the study. That said, we are now fully engaged in recruitment and implementation of the RCT; we anticipate being able to recruit, treat, and assess our target of n=150 suicidal Soldier-participants within the proposed study timeframe.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in *Science, Military Medicine*, etc.).

None at this time.

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Please note the attached revision of the CAMS Training Manual, the SSF-IV, and the CAMS Rating Scale that have been further developed and refined in the course of this study.

SUPPORTING DATA: All figures and/or tables shall include legends and be clearly marked with figure/table numbers.